Department of Health

Consultation on Amendments to the Statutory Scheme to Control the Prices of Branded Health Service Medicines

Consultation on Amendments to the Regulations Underpinning the Statutory Scheme

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Chapter 1 Introduction

Pharmaceutical Price Regulation Scheme

1.1. The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement made between the Department of Health, on behalf of the UK Government and Northern Ireland and the Association of the British Pharmaceutical Industry (ABPI). The PPRS supports the NHS by ensuring that the branded health service medicines bill stays within affordable limits. It aims to strike a balance to promote the common interests of patients, the NHS, the industry and the taxpayer.

1.2. The PPRS covers all licensed, branded, health service medicines supplied by members of the scheme. It does not cover:

- sales of products on private prescription or other use outside the health service in the UK;
- products without a brand name (generics);
- branded products available without prescription (over the counter (OTC) medicines), except when these are prescribed.

1.3. In 2013 a new scheme was negotiated between the Department of Health and the ABPI and the 2014 PPRS commenced on 1 January 2014 (available at https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014).

1.4. The 2014 scheme provides greater certainty on the maximum the NHS will spend on branded health service medicines while continuing to provide timely access to medicines for patients. Under the 2014 scheme, the vast majority of branded health service medicine spend will remain flat for two years, followed by small increases of less than two per cent for three years. Companies that are members of the scheme make payments to the Department of Health to ensure that spending on branded health service medicines stays at the agreed level.

Statutory price control

1.5. In 2008, the Department of Health consulted on the introduction of regulatory provisions to put in place statutory price limits on the sales of prescription only, branded health service medicines by companies that choose not to be members of the voluntary PPRS agreement. The purpose was to safeguard the financial position of the NHS by ensuring that there would be similar limits in the statutory scheme to the PPRS on the cost of prescription only, branded health service medicines supplied by companies that decided not to join the PPRS.

1.6. The Secretary of State's primary powers to limit the prices of, or the profits accruing from, health service medicines, are set out in sections 261-266 of the National Health Service Act 2006.[1] Regulations setting out the requirements for the statutory scheme are set out in the Health Service Branded Medicines (Control of Prices and

[1] http://www.legislation.gov.uk/ukpga/2006/41/contents

Supply of Information) (No.2) Regulations 2008 ['2008 Regulations'][2], and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 ['2007 Regulations'], as amended.[3] These Regulations have been amended by the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013 ['2013 Regulations'].[4]

1.7. The principal elements of the statutory scheme include:

- Establishing a maximum price which can be charged for the supply of prescription only, branded health service medicines, and making provision for adjustments to this price;
- Setting out the information which companies are required to provide to enable price limiting mechanisms to operate;
- Providing for certain exemptions to elements of the scheme in relation to low cost presentations; and
- Setting out provisions to cover the enforcement of the scheme.

Statutory scheme – 2014 Amendments

1.8. In 2013, the Department of Health consulted on proposals to amend the 2007 Regulations and the 2008 Regulations. The 2013 Regulations came into force on 1 January 2014.

1.9. The amendments bring the statutory scheme into better alignment with the PPRS, and include the following key changes:

i. a 15% reduction in the maximum price of branded health service medicines that were on sale on 1 December 2013;

ii. the removal of the £450k low-cost presentation exemption, in order to capture sales from companies selling into secondary care;

iii. revised information requirements requiring companies to provide annual information on sales income and discounts.

1.10. The Department also consulted on proposals to apply price limits to average selling prices in secondary care, including line extensions. In our response to the consultation, we acknowledged the complexities around this issue and the concerns raised by respondents. We have decided to give these issues further consideration and will therefore not be discussing these proposals at this time.

[2] www.legislation.gov.uk/uksi/2008/3258/contents/made
[3] www.legislation.gov.uk/uksi/2007/1320/contents/made6
[4] http://www.legislation.gov.uk/uksi/2013/2881/contents/made

Current proposals

1.11. This consultation concerns options for:

- a further limit to the maximum price of prescription only, branded health service medicines with reference to the price at which the presentation was on sale for health service purposes on 1 December 2013;
- strengthening the information requirements for enforcement to enable fair and consistent application of the limit on price.

1.12. It is on these two issues that we are seeking comments. If, following this consultation and our consideration of the responses, we decide to go ahead with a further limit to the maximum price and/or strengthening of the information requirements this will be done via amendments to the 2008 and 2007 Regulations.

1.13. In addition to the proposals set out above we expect to make two technical changes to the 2008 Regulations in order to clarify the position in respect of ‘over the counter’ medicines (where we intend to revert to the position prior to the 2014 amendments) and in respect of the application of the regulations to certain framework agreements tendered under European and UK procurement law (see paragraph 2.15 below). These two matters do not however form part of the consultation.

Chapter 2 Proposed amendments

Price adjustment

Introduction

2.1. The Government response to the consultation on the 2013 Regulations said that having taken into account all the issues, including the state of public finances and the Heads of Agreement for the 2014 PPRS, it would be appropriate to implement a cut of 15% on the maximum price of presentations that were on sale for health service purposes on 1 December 2013. This came into effect on 1 January 2014.

2.2. The 2014 PPRS referred to an intention "to consult on amendments to the statutory scheme regulations to apply to companies that leave the [voluntary] scheme at any stage from the time that new regulations applied to ensure that the price cuts applied to those new members of the statutory scheme reflect at a minimum the level of payment they would otherwise have paid in the scheme".

2.3. The Government is now considering whether a further limit on the maximum price would be appropriate. We are particularly interested in the impact this might have on small companies.

Options

2.4. We are consulting on further limiting the maximum price of prescription only, branded health service medicines so that the maximum price which may be charged for the supply of a presentation would be the price at which that presentation was on sale for health service purposes on 1st December 2013 less 15%-25%, without regard to any discount or other variation in price which did not have general application on that date. In other words, the range consulted on is from 0 to 10 percentage points' further downward adjustment in addition to the current 15% reduction in the maximum price.

2.5. The factors that the Department will take into account in setting the price limit are as follows:

- The challenging NHS financial position in 2015. The overall Department of Health expenditure limit will increase from £113.0 billion in 2014/15 to £115.1 billion in 2015/16 of which £3.8 billion is to be pooled between health and social care budgets.
- The requirement under the European Transparency Directive to carry out a review at least once a year to ascertain whether the macro-economic conditions justify that the price cut be continued or that a further price cut is required. We propose to keep the statutory scheme in broad alignment with the 2014 PPRS, which aims to strike a balance to promote the common interests of patients, the NHS, the industry and the tax payer. The agreed objectives of the 2014 PPRS include keeping the branded health service medicines bill within affordable limits, improving access to clinically-effective and cost-effective medicines and supporting the Government's growth and innovation agenda for life sciences.

- The growth in the branded medicines bill. The forecast agreed as part of the 2014 PPRS was for growth of 3.87% in calendar year 2014 and 3.52% in 2015. The actual growth rate recorded for the first half of 2014 as part of the PPRS Payment Mechanism was 5.5%.[5]
- The need to align broadly the effect of the statutory scheme in limiting prices to the effect of the voluntary PPRS while taking account of the differences between the two schemes. The statutory scheme price adjustment is applied to the maximum price which may be charged for the supply of a presentation, without regard to any discount or other variation of the price which did not have general application on the reference date of 1 December 2013. By contrast the PPRS limits total eligible spend and the payments made by companies apply to net sales after discounts have been applied. The profiled PPRS Payment percentage in 2015 is 7.13% and for the last three years of the scheme 9.92%, based on the initial agreed forecasts of annual growth. The PPRS includes an automatic mechanism to adjust the payment percentage profile to take account of differences in actual growth rate compared to forecast.
- We have concluded that developing provisions aimed specifically at companies that leave the voluntary scheme would be complex and might lead to undesirable behaviour. We do, however, consider it important to encourage companies to remain in the voluntary scheme in order to maintain the stability and predictability provided by the PPRS limit on growth in the branded health service medicines bill. This is a further argument for continuing to align the statutory scheme broadly with the PPRS so that the price cut reflects at a minimum the level companies would otherwise have paid in the PPRS.
- The cost of research and development. The 2014 PPRS encourages innovation and the development of high value treatments by promoting a strong and profitable pharmaceutical industry that is both capable of and willing to invest in sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and the industry in this and other countries.

2.6. The adjusted PPRS Payment profile will be announced in quarter 4 of 2014. In setting the price adjustment for the statutory scheme we will take into account the relevant factors, as set out above, including the adjusted PPRS Payment profile, and the responses to the consultation. We propose that any further price adjustment should come into effect no earlier than 1 February 2015.

1) Comments are invited on the range of potential price adjustments.

2) We welcome views on the above factors and any other considerations the government should take into account when considering whether and to what extent further limits on the cost of branded health service medicines should be applied, for example the impact that any price

[5] Based on latest data, subject to data changes.

adjustment might have on companies that are close to the £5m exemption threshold.

Strengthening the information requirements for enforcement

2.7. Provisions for enforcement of the limit on maximum prices for branded health service medicines are set out in Regulation 7 and Schedule 1 to the 2008 Regulations. A manufacturer or supplier who supplies a prescription only, branded health service medicine at a price in excess of the maximum permitted in the Regulations is liable to pay on demand a recoverable sum calculated in accordance with the Schedule to the Regulations. The recoverable sum is calculated on the basis of the difference between the amount which a company would have received had the product been supplied at the maximum permitted price and the amount that the company actually received.

2.8. The 2013 Regulations amended the information requirements set out in the 2007 Regulations. Under Regulation 3, as amended, a manufacturer or supplier of branded health services medicines must, to the extent that the information is available to it, provide the Secretary of State with information on the sales income in respect of each presentation and the total number of these presentations, and any discounts that were applied, on a regular basis (annually from 2015 onwards) and within a specified time period.

2.9. The Department is able to identify if there is evidence that there has been a breach in the limit on maximum price by monitoring NHS list prices which are provided to the Department or, in rare cases where there is no published NHS list price, by monitoring the average selling price of presentations using information provided under the revised information requirements set out above.

2.10. However, for the purposes of enforcement and the ability to calculate a recoverable sum at any time, the Department considers there is a need to strengthen the information requirements further. The aim is to improve the Department's ability to apply the limit on maximum price in a fair and consistent way. We are proposing amending the information requirements in the 2007 Regulations in order to enable the Department effectively to carry out enforcement action should that be necessary.

2.11. We propose that the regulations should be amended to impose additional requirements on manufacturers and suppliers to:

(a) record and keep information on the actual price charged for each sale of each of their presentations covered by the Regulations, on a continuous basis, and

(b) provide, on request, information to the Department setting out the actual amount charged for specified presentation(s) and for specified time period(s) as set out in writing by the Department.

This would enable the Department to confirm whether or not a breach has in fact occurred (if this is in doubt) and if so to make an accurate demand for payment of the recoverable sum.

2.12. We propose that the current exemption from the information requirements for manufacturers and suppliers with sales income of less than £5 million for branded health service medicines should apply to these new information requirements. We also propose that the schedule of penalties in the 2007 Regulations will apply to these new information requirements.

2.13. We anticipate that companies already record this information for accounting purposes and this should not create a significant additional administrative burden. The Regulations would make clear that companies would only be required to provide the information on demand if the Department suspected a possible breach.

3) Should manufacturers and suppliers be required to record and keep information on actual selling prices of branded health service medicines in order to strengthen the Department's ability to enforce the scheme where necessary and support a fair and consistent application when necessary?

4) Do you agree that manufacturers and suppliers already record this information?

5) Do you agree that manufacturers and suppliers should be required to supply this information on demand? If you have concerns regarding administrative burden, it would be helpful if you could provide a realistic level of costs for supplying the information.

6) Do you agree that penalties should be applied to these new information requirements?

Other Comments

7) Do you have any other comments about the consultation proposals?

Over the counter (OTC) Medicines

2.14. On 19 May 2014, the Department published the following statement:

> *The Department's policy is that over the counter (OTC) medicines should not be covered by the regulations which control the prices of medicines supplied to the NHS (the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008). However, this was not made clear in the Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013. The amendment apparently extended the scope of the statutory controls on prices Regulations beyond prescription only medicines and applied the limit on the prices of health service medicines supplied by manufacturers and suppliers subject to the Regulations to over the counter medicines which are supplied to the NHS. This was not the Department's policy intention. We will not enforce those regulations in relation to OTC medicines, and will amend the regulations at the next appropriate opportunity to reflect this.*

We are now confirming our intention to amend the regulations to make clear that the limit on price only applies to prescription only medicines supplied to the health service.

Clarification of the effect of procurement law

2.15. An issue has been raised about the application of the regulations to certain framework agreements tendered under European and UK procurement law. We intend to clarify the regulations in this regard. We are not seeking views on this issue as it is a matter of clarifying the application of existing law.

Chapter 3 Responding to the consultation

Responding to the consultation

You can respond to this consultation by post or by email. You can send your response by hard copy to:

Statutory Pharmaceutical Pricing Scheme Consultation
c/o Cathleen Schulte
Ground Floor North
Wellington House
133-155 Waterloo Road
London
SE1 8UG

Or by email to: Cathleen.Schulte@dh.gsi.gov.uk

The consultation closes on 7 November 2014.

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Contact
Consultations Coordinator
Department of Health
2E26, Quarry House
Leeds
LS2 7UE

E-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Personal information charter - Department of Health - GOV.UK.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information

Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.